Section 5. 510(k) Summary

K Number K123729

DEC 2 1 2012

Submission Date: 11/6/12

General Information

Classification	Class II
Trade Name	VersaRate™ Flow Rate Controller
Common Name:	I.V. Flow Controller
Classification Name and Reference:	Intravascular Administration Set 21 CFR §880.5440
Submitter	Peter Kollings EMED Technologies Corporation 1264 Hawks Flight Ct., Ste. 200 El Dorado Hills, Ca 95762 Tel: 916.932.0071 x114 Fax: 916.932.0074

Intended Use

The VersaRate™ Flow Rate Controller is intended for use in the intravascular infusion of fluids to be delivered to the patient in a precise manner for no longer than 72 hours.

Predicate Device(s)

Baxter Extension Set w/Flow Regulator (K890489)

Device Description

The EMED VersaRate™ Flow Rate Controller is a disposable device allowing users to adjust the flow rate of fluids. The EMED VersaRate™ Flow Rate Controller can be connected to commercially available administration sets and fluid sources utilizing standard luer lock connectors.

Materials and Characteristics

The EMED VersaRate™ Flow Rate Controller is equivalent in performance, physical properties, using similar materials, and having the same indications for use as the

predicate device. Therefore no new issues of safety or effectiveness are introduced by the minimal differences in design.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED VersaRate™ Flow Rate Controller and the predicate.

Table 5-1

	EMED VersaRate™ Flow Rate Controller	**Baxter Extension Set w/Flow Regulator**
Indications for Use	The VersaRate™ Flow Rate Controller is intended for use in the intravascular infusion of fluids to be delivered to the patient in a precise manner for no longer than 72 hours.	The Extension set with Flow Regulator is intended for use in the administration of intravenous fluids to be delivered to the patient in a precise manner over a specified period of time.
Flow Control Material/Components	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Tubing: PVC Regulator: Polycarbonate and styrene-ethylene-butylene	Biocompatible, non-toxic materials widely used in medical products.
Method of Sterilization	Ethylene Oxide	Radiation
Principle of Flow Rate Control	The fluid path of the VersaRate™ Flow Rate Controller is regulated by rotating the flow dial to alter dimensions of the internal fluid path, thereby altering the flow rate.	Fluid flow is regulated by rotating the diaphragm holder to create a restrictive path of varying depth thereby altering the rate of fluid administration.
Length	16 cm	46 cm

Performance

Table 5-2 below summarizes testing results performed to establish conformance of the VersaRate™ Flow Rate Controller to internal product specifications and requirements, as well as equivalence to the predicate device.

Table 5-2

	VersaRate™ Flow Rate Controller	**Baxter Extension Set w/Flow Regulator**
Flow Rate Control Range	5 – 230 mL/hr at 80 cm head height	5 – 250 mL/hr
Residual Volume of Set	< 0.25 ml	2.9 mL
Duration of Use	Performance remains within tolerance up to 72 hrs.	Performance remains within tolerance up to 24 hrs.
Pressure	Up to 25 psi	Up to 3 psi

The outcomes of these tests further indicate that the VersaRate™ Flow Rate Controller is substantially equivalent to the predicate in performance, effectiveness, and safety.

Biocompatibility

In accordance with ISO 10993, studies were performed including cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility. Table 5-3 presents a summary of testing and results indicating compliance with biocompatibility standards.

Table 5-3

Test Performed	Standard	Test Name	Test Result	Other Name
Biocompatibility	ISO 10993-5	Cytotoxicity	Pass	Neutral Red Uptake
Biocompatibility	ISO 10993-10	Sensitization	Pass	Kligman Maximization
Biocompatibility	ISO 10993-10	Irritation	Pass	Intracutaneous Injection
Biocompatibility	ISO 10993-11	Acute systemic toxicity	Pass	Systemic Injection
Biocompatibility	ISO 10993-11	Pyrogenecity	Pass	Rabbit Pyrogen
Biocompatibility	ISO 10993-4	Hemocompatibility	Pass	Unactivated Partial Throbmoplastin Time
Biocompatibility	ASTM 756	Hemocompatibility	Pass	Hemolysis (complete)

Sterility, Shelf-life, and Packaging

The VersaRate™ Flow Rate Controller will be sterilized to a sterility assurance level (SAL) of 10^{-6} and with a shelf life of 4 years.

Summary of Substantial Equivalence

The EMED Technologies Corporation VersaRate™ Flow Rate Controller is substantially equivalent to the commercially available predicate device in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Differences between the EMED VersaRate™ Flow Rate Controller and the predicate do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2012

EMED Technologies Corporation
C/O Mr. Morten S. Christensen
Staff Engineer
Underwriters Laboratories, Incorporated
455 East Trimble Road
SAN JOSE CA 95131-1230

Re: K123729
Trade/Device Name: VersaRate™ Flow Rate Controller
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 29, 2012
Received: December 5, 2012

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use Statement

510(k) Number (if known): [TBD] K123729

Device Name: VersaRate™ Flow Rate Controller

Indications for Use: The VersaRate™ Flow Rate Controller is intended for use in the intravascular infusion of fluids to be delivered to the patient in a precise manner for no longer than 72 hours.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/19/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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